

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1-39 (Canceled)

40. (Previously presented) A drug delivery system according to claim 44, wherein said dermal penetration enhancer is one or more esters selected from the group consisting of C₈ to C₁₈ alkyl para-aminobenzoate, C₈ to C₁₈ alkyl dimethyl-para-aminobenzoate, C₈ to C₁₈ alkyl cinnamate, C₈ to C₁₈ alkyl methoxycinnamate and C₈ to C₁₈ alkyl salicylate.

41-43 (Canceled)

44. (Currently amended) A non-occlusive, percutaneous or **non-occlusive** transdermal drug delivery system which comprises:

- (i) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof;
- (ii) at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof;
- (iii) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer;

wherein:

the dermal penetration enhancer (A) is adapted to transport the physiologically active agent across a dermal surface or mucosal membrane of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface or membrane, and (B) is of low toxicity to, and is tolerated by, the dermal surface or mucosal membrane of the animal; and,

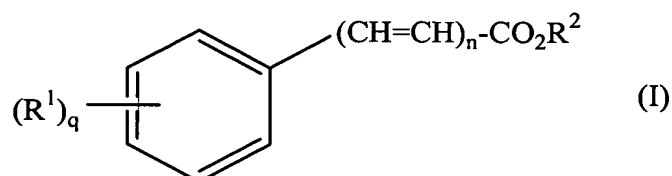
after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within 3 minutes of application.

45. (Previously presented) A drug delivery system according to claim 44, wherein the drug delivery system is not supersaturated with respect to the physiologically active agent.

46. (Previously presented) A drug delivery system according to claim 44, wherein the dermal surface or mucosal membrane becomes touch-dry within 1 minute of application.

47. (Previously presented) A drug delivery system according to claim 44, wherein the dermal penetration enhancer is a safe skin tolerant sunscreen.

48. (Previously presented) A drug delivery system according to claim 44, wherein said dermal penetration enhancer is an ester of formula (I):



wherein R^1 is hydrogen, lower alkyl, lower alkoxy, halide, hydroxy or NR^3R^4 ;

R^2 is a long chain alkyl;

R^3 and R^4 are each independently hydrogen, lower alkyl or R^3 and R^4 together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

n is 0 or 1; and

q is 1 or 2.

49. (Previously presented) A drug delivery system according to claim 44, wherein said dermal penetration enhancer is one or more esters selected from the group consisting of a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate and long chain alkyl salicylate.

50. (Previously presented) A drug delivery system according to claim 49, wherein said dermal penetration enhancer is one or more esters selected from the group consisting of octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate and octyl salicylate.

51. (Previously presented) A drug delivery system according to claim 44, wherein the volatile liquid is ethanol or isopropanol.

52. (Previously presented) A drug delivery system according to claim 44, wherein the physiologically active agent is a steroid, hormone derivative, non-steroidal anti-inflammatory drug, opioid analgesic, antinauseant, antioestrogen, aromatase inhibitor, 5-alpha reductase inhibitor, anxiolytic, prostaglandin, anti-viral drug, anti-migraine compound, antihypertensive agent, anti-malarial compound, bronchodilator, anti-depressant, anti-Alzheimer's agent, neuroleptic and antipsychotic agent, anti-Parkinson's agent, anti-androgen or anorectic agent.

53. (Previously presented) A drug delivery system according to claim 44, wherein the physiologically active agent is testosterone, oestradiol, ethinyloestradiol, progesterone, norethisterone acetate, ibuprofen, ketoprofen, flurbiprofen, naproxen, diclofenac, fentanyl, buprenorphine, scopolamine, prochlorperazine, metochlopramide, ondansetron, tamoxifen, epitiostanol, exemestane, 4-hydroxy-androstenedione and its derivatives, finasteride, turosteride, LY191704, MK-306, alprazolam, alprostadil, prostacyclin and its derivatives, melatonin, n-docosanol, tromantadine, lipophilic pro-drugs of acyclovir, low molecular weight heparin, enoxaparin, sumatriptan, amlodipine, nitrendipine, primaquine, minoxidil, minoxidil pro-drugs, pilocarpine, salbutamol, terbutaline, salmeterol, ibogaine, bupropion, rolipram, tacrine, fluphenazine, haloperidol, N-0923, cyproterone acetate or mazindol.

54. (Previously presented) A drug delivery system according to claim 44, wherein the system is applied to the dermal surface by an aerosol, as a spray.

55. (Previously presented) A drug delivery system according to claim 54, wherein the aerosol is a fixed or variable metered dose aerosol.

56. (Previously presented) A drug delivery system according to claim 44, further comprising a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent or a mixture of two or more of said components.

57. (Previously presented) A method for administering at least one systemic or locally acting physiologically active agent or prodrug thereof to an animal which comprises applying an effective amount of the physiologically active agent in the form of a drug delivery system according to claim 44 to a dermal surface or mucosal membrane of said animal.

58. (Currently amended) A method for the treatment ~~or prophylaxis~~ of a disease or condition in an animal which comprises administering to a dermal surface or mucosal membrane of said animal in need of such treatment a therapeutically effective amount of the drug delivery system according to claim 44 to a dermal surface or mucosal membrane of said animal.

59. (Currently amended) A method according to claim 58, wherein the method is for the treatment of a disease or condition selected from the group consisting of a disease or condition that requires male hormone replacement in testosterone deficient hypogonadal men, a disease or condition that requires female hormone replacement therapy for postmenopausal women, a disease or condition that requires androgen replacement therapy for females lacking libido, ~~male~~

~~contraception or female contraception, a soft tissue injury, narcotic withdrawal, severe post-operative pain, oestrogen dependent breast cancer, prostatic enlargement, prostatic cancer, alopecia, an anxiety disorder, male impotence, Raynaud's syndrome, varicose veins, a sleep disorder, herpes virus infection, deep vein thrombosis, migraine, high blood pressure, and malaria.~~

60. (Currently amended) A method according to claim ~~58~~ 57, wherein the animal is suffering from or at risk of developing a disease or condition selected from the group consisting of ~~is soft tissue injury, narcotic withdrawal, severe post-operative pain,~~ motion sickness, ~~oestrogen dependent breast cancer, prostatic enlargement and/or prostatic cancer, alopecia and~~ acne, ~~anxiety disorders, male impotence, Raynaud's syndrome and varicose veins, sleep disorders,~~ jetlag, ~~herpes virus infections, deep vein thrombosis, migraine, high blood pressure, malaria, diagnosis of cystic fibrosis,~~ asthma ~~or~~ and nocturnal asthma.

61. (Previously presented) A method according to claim 57, wherein the animal is a human.

62. (Canceled)

63. (Previously presented) A transdermal drug delivery system according to claim 44, wherein the physiologically active agent or prodrug thereof, the dermal penetration enhancer, and the volatile liquid are a single phase.

64. (Previously presented) A method according to claim 57, wherein the drug delivery system is applied by an aerosol or spray comprising a shroud adapted to keep an actuator nozzle of the apparatus at a pre-determined height above the site of application.

65. (New) A method according to claim 57, wherein the animal is in need of male contraception or female contraception.

66. (New) A method according to claim 57, wherein the physiologically active agent or prodrug thereof is administered for the diagnosis of cystic fibrosis.